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10/692,996	10/24/2003	Jay Prabhakar Gore	3220-73780	9342

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EXAMINER	
GAKH, YELENA G	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,996	GORE ET AL.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,11,16-23 and 25-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,11,16-23 and 25-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. RCE and amendment filed on 09/15/08 are acknowledged. Claims 6-10, 12-13 and 24 are additionally cancelled. Thus, claims 1-5, 11, 16-23 and 25-69 are pending in the application.

Response to Amendment

2. The amendments filed on 03/10/08 and 09/15/08 are objected to under 35 U.S.C. 132(a) because they introduce new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "an optical sensor" and "optical detection". The Applicants obviously differentiate between detecting electrical signal and optical detection. No optical detection or detector (sensor) has been disclosed in the specification as originally filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

3. Objection to the claims and warning regarding duplication of claim 2, are withdrawn. Rejections under 35 U.S.C. 112, first and second paragraph, and over the prior are, are modified in view of the amendment. Rejection of pending claims over double patenting, is maintained.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 11, 16-23 and 25-69 of the instant application are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 7,288,768 in view of Cupp et al. (US 6,219,565) (Cupp). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims recite essentially the same subject matter for the method of detecting an organic compound, in particular glucose in the instant application and fat in the patent, using IR spectroscopy with converting optical signals from several absorption ranges into electrical signals with the following processing of the signals using a multivariant calibration algorithm. The only difference between the pending claims and those of the issue patent is the step of transmitting incoherent IR radiation. However, transmitting incoherent radiation is well known in the art, as can be seen from e.g. US 6,219,565, which discloses "a cost-effective probe which combines the *low-cost advantages* of an **incoherent fiber optic bundle for the transmitting fibers** with the advantages of coherently arranged receiving fibers in the bundle".

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 19-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 19-22 recite that "the mean-centered concentration of glucose in said

biological fluid being calculated with the equation: ...". The specification discloses: "C_g is the mean centered concentration of glucose in solution measured using methods other than IR absorption" (see paragraphs [00158], [00164], [00165] and [00170]). Moreover, the specification discloses that the equations (1)-(4) utilize the known C_g values in order to obtain calibration coefficients P_1-P_n (n=1-9) for further application of the calibration algorithm in determining an unknown amount of glucose. This discrepancy raises reasonable doubts as to possession of the invention recited in claims 19-22 at the time of filing the application.

7. Claims 26, 27 and 57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for known organic compound with known IR spectrum, does not reasonably provide enablement for the unknown organic compound with the unknown IR spectrum. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. There is no way for a person of ordinary skill in the art to illuminate the biological sample with IR radiation at discrete wavelength bands which correspond to the absorption bands of the organic compound, or to apply spectral filters specifically to transmit the signals in the absorbance wavelengths, if these wavelengths are not preliminary known.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 11, 16-23 and 25-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 17, 23 and 28 recite "optical sensor". The originally filed specification does not disclose any "optical sensor" (optical detector). By definition, "an optical detector: a transducer that generates an output signal when irradiated with optical energy (188). Aug 23, 1996: (http://www.its.bldrdoc.gov/fs-1037/dir-025/_3711.htm. This definition includes the means for generating an electrical signal. It is not apparent, as to what type of optical sensor the Applicants mean in the recitation of the claims, since any optical sensor can generate electrical signal. Do they recite any specific optical sensor? Since no specific definition for "optical

sensor (detector)" is provided in the instant specification, the examiner interprets the term according to its conventional usage.

It appears that claims 19 and 20, and claims 21 and 22 should be paired, and thus recite IAR and IA in each pair, respectively. Otherwise, it is not clear, how the equations relate to each other. The examiner suggests exchanging the subject matter of claims 20 and 21 with each other.

Several claims recite "the optical detector measures the intensity of radiation at less than 10 discrete wavelength bands". This expression is not definite, since there is a plurality of ways the optical detector can measure the intensity of radiation at discrete wavelengths including post-detected processing of the signal, which would still be considered "measuring of the intensity of radiation". Since such claims as 28 do not specifically recite any spectral filtering of the signals transmitted by the sample, the examiner interprets them in the broadest sense, i.e. as any operation that allows measuring discrete wavelengths bands.

Claims 57-69 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: modulating mid-infrared radiation before transmitting modulated mid-infrared radiation in claim 57.

Furthermore, it is not apparent, as to which modulation of mid-infrared radiation is meant in the claim, and where the mid-infrared radiation was obtained from, since no mid-infrared radiation was recited in the previous steps.

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. **Claims 1-5, 11, 16-23 and 25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lillenfeld-Toal (US 6,484,044) as evidenced by Peralta et al. (J. Phys. E. Sci., 1988) in view of Cupp et al. (US 6,219,565) (Cupp).

Lillenfeld-Toal teaches a method of measuring an amount of an organic substance (glucose) (*claim 2*) contained within a biological sample, the compound having an infrared absorption spectrum, which includes a set of wavelength regions (see Figure 3), the method comprising detecting a number of selected wavelength bands from the spectrum less than the

total number of the wavebands of the compound: for example detecting at least three different wavelengths (col. 4, lines 1-2) of selected wavenumbers 1151, 1105, 1080, 1036 and 992 cm^{-1} (col. 4, line 15) (corresponding to detecting in the regions recited in *claims 6-8 and 14-16*); generating an electrical signal in photoacoustic sensor (in piezoelectric transducer 6, col. 3, lines 44-45) in response to detecting the intensity of the bands at these wavenumbers; and processing said electrical signal with a quantification algorithm, e.g. "by a least square calculation referring to reference spectra such as shown in FIGS. 2 or 3 for known glucose concentrations. The calculated concentration is displayed on display 9. Alternatively, the glucose concentration could also be calculated from an average of concentrations obtained from the absorptions at each wavelength relative to reference absorption for a reference glucose concentration determined beforehand" (col. 4, lines 26-34) (*claims 1 and 3-5*). Equations recited in *claims 19-22* are conventional equations for partial least square analysis with the number of contributions defined by the number of input wavelengths.

Peralta et al. describe photoacoustic detector disclosed by Lillenfeld-Toal as an optical detector, i.e. "photoacoustic optical power meter using piezoelectric detection" (Title).

Lillenfeld-Toal does not specifically disclose transmitting incoherent IR radiation.

Cupp discloses "a cost-effective probe which combines the low-cost advantages of an **incoherent fiber optic bundle for the transmitting fibers** with the advantages of coherently arranged receiving fibers in the bundle. In contrast to the prior art, the present invention is designed to operate in intimate contact with its intended target, i.e., the human skin, and deliberately avoids direct surface reflections. In a preferred embodiment, the probe combines an incoherent transmissive fiber optic bundle with a small number of spaced receiving fibers arranged in a specialized, regular pattern to optimize received-signal intensity in a glucose measurement application. A preferred embodiment also includes uniquely designed features to thermally and/or mechanically isolate the receiving fibers extending from the probe in order to enhance their operation in a glucose measurement application." (Col. 2, Summary of the Invention, lines 9-25).

It would have been obvious for a person of ordinary skill in the art to modify Lillenfeld-Toal's method by utilizing incoherent fiber optic bundle for the transmitting fibers disclosed by

Cupp to transmit incoherent infrared radiation, because, as Cupp specifically indicated it is a cost-effective light transmitting element.

11. **Claim 26** is rejected under 35 U.S.C. 103(a) as being unpatentable over anyone of Heise et al. (Appl. Spectr., 1994) (Heise), Bhandare et al. (Appl. Spectr., 1994) (Bhandare), Budinova et al. (Appl. Spectr., 1997) (Budinova), or Vonach et al. (Appl. Spectr., 1998) (Vonach) in view of Sterling et al. (US 6,025,597, IDS) (Sterling).

All references disclose a method of measuring a glucose level within a biological sample using mid-infrared spectroscopy by measuring a set of wavelength regions, in which glucose absorbs in mid-IR range: 1200-950 cm^{-1} (see e.g. Heise, page 88, left column) by obtaining a sample of a biological fluid, passing an incident signal of indicated wavelength through the sample, detecting a post-absorbance signals and calculating glucose concentration from said post-absorbance signal. All references disclose detecting glucose at specific wavelengths: "for glucose, the best predicting results were achieved within the rather narrow spectral range of 1200 to 950 cm^{-1}, where the most intensive absorption bands of aqueous glucose exist" (Heise, page 88, left column); Budínova discloses the following wave-numbers for glucose, which slightly differ from the ones recited in the claims: 1035, 1078, 1104 and 1148 cm^{-1} with the full range of 1185-950 cm^{-1}; Vonach indicates that "the spectral change [upon adding glucose] is in accordance with the glucose absorption with its maxima at 1038 and 1080 cm^{-1}" (page 821, left column).

Heise, Bhandare, Cadet, Budínova or Vonach do not specifically disclose using spectral filtering for discrete detecting the signals at discrete wavelength bands of glucose.

Sterling discloses a wavelength selection system for selecting specific wavelengths of IR spectra, specifically discrete infrared bandpass filters (col. 10, lines 46), indicating the following:

> "The use of a specific set of bandpass filters restricts the instrument to analyzing only pre selected wavelengths. The use of the FTIR allows the optical measurements of all wavelengths. When using an FTIR the final analysis wavelengths are selected in the signal processing computer. Therefore an instrument built with discrete filters is dedicated to measuring a predetermined compound, e.g. glucose, while an instrument built using an FTIR can be directed via software modifications to measure any of a number of compounds such as glucose, alcohol, etc." (col. 10, lines 57-67).

Thus, Sterling provides direct disclosure for both types of methods, i.e. the method of using FTIR instrument with post-detected processing the signals related to the analyte, e.g.

glucose, or method of using spectral filters build-in into the IR spectrometer for the specific analyte, e.g. glucose, which makes the modification of any of the teachings provided above for FTIR analysis of glucose obvious for a person of ordinary skill in the art.

12. **Claim 27** is rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke (US 5,054,487).

Clarke discloses the following:

> Systems and methods for material analysis are disclosed in which a material (e.g., **a liquid such as blood**) is illuminated **at a plurality of discrete wavelengths**. Measurements of the intensity of reflected light at such wavelengths are taken, and an analysis of reflection ratios for various wavelengths is performed. Changes in the reflection ratios can be correlated with specific material properties such as the concentration of analytes (e.g., oxygen content, **glucose levels**, cholesterol or drugs in a subject's circulatory system). In one aspect of the invention, an analytic apparatus and method are described employing a multi-wavelength illumination source, a wavelength specific detector array, and a reflection ratio analyzer. **The illumination source illuminates a material sample at a plurality of discrete wavelengths. The detector array detects the light reflected from the sample, converts the detected light into electrical signals indicative of the intensity of the reflected light at each wavelength, and transmits the converted signals to a reflection ratio analyzer**. The reflection ratio analyzer then derives a reflectance ratio for at least two of the detected wavelengths, such that the ratio can be compared with predetermined values to detect the presence and/or concentration of an analyte in a material sample. *Although the illustrated embodiment shows a system with a fiber optic bundle for delivery of six distinct wavelengths of light, it should be clear that the number of interrogation wavelengths, the size and shape of the sampling head and the means for transmitting the light to and from the sample can be varied to meet particular needs and applications. In particular, a single fiber can be used for transmission and detection of multiple interrogation wavelengths. Moreover, although lasers are described as preferred light sources, other illumination means including non-coherent, discrete wavelength light sources can be employed.*" (Col. 1, lines 59-69 and col. 2, lines 1-16).

While Clarke does not specifically teach irradiating the sample with the discrete wavelengths corresponding to the absorption spectrum of the organic compound, it would have been obvious for a person of ordinary skill in the art to modify Clarke's method by narrowing down selected discrete wavelengths in order to irradiate the sample with the wavelengths closest to absorption signals of the organic compound under analysis in order to exclude the spectral lines of interfering compounds, and in order to determine the reflection ratio in a more precise way.

13. **Claims 28-51 and 56** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lillenfeld-Toal as evidenced by Peralta in view of Cupp and Purdy et al. (US 5,460,177) (Purdy).

Disclosure of Lillenfeld-Toal as evidenced by Peralta in view of Cupp can be read in paragraph 10 of the present Office action.

Lillenfeld-Toal/Peralta-Cupp do not specifically teach modulation of infrared radiation.

However, overheating the biological sample with intensive NIR or mid-IR radiation is a problem in analysis of component of biological sample, as discussed by Purdy.

Purdy indicates: "[c]ontinuous-spectrum noninvasive techniques make use of radiation in the near-infrared portion of the spectrum. However, in this portion of the spectrum, the absorption of radiation by water is very high. In addition, the concentrations of the analyte of interest in the bloodstream is typically low. As a result, the contribution of the analyte of interest to the signal intensity is only a relatively small change in the total signal intensity obtained by this technique. It has been found that detector noise is of the same order of magnitude as the change in intensity signal resulting from variations in analyte concentration. The variations in signal intensity as a result of variations in concentration of the analyte of interest are so small that, at intensities that have been used in the past, the detector's sensitivity may not be high enough to obtain sufficiently accurate readings. A possible solution to this problem would be to increase the intensity of the radiation incident on the body part of the subject. However, an increase in the intensity of incident radiation increases the amount of energy absorbed by the body part. Increases in the energy absorbed by the body part result in greater heating of the body part the amount of heat produced. Excessive heating can cause discomfort and even burns to the subject, which obviously would be undesirable. It is accordingly an object of this invention to provide a method for the continuous spectrum non-invasive spectroscopic detection of analytes in the bloodstream of living animals with increased signal-to-noise ratio" (col. 1, lines 64-67 and col. 2, lines 1-25).

Purdy provides a solution to the problem by using a chopper for periodically interrupting radiation emitted from the bulb, i.e. modulating intensity of the incident signal: "A method for non-invasive detection of the concentration of an analyte in the blood of a living animal includes the steps of irradiating a body part of the animal with intensity-modulated radiation over a

continuous spectrum; detecting the intensity of radiation emitted from the body part at a plurality of discrete wavelength ranges within the continuous spectrum; and using the detected intensity to calculate the concentration of the blood analyte" (col. 2, lines 31-39) The chopper by definition is a device which periodically blocks the infrared radiation, and therefore can have any structure comprising IR transparent and non-transparent parts.

It would have been obvious for any person of ordinary skill it the art to modulate intensity of the incident signal as taught by Purdy in Lillenfeld-Toal/Peralta-Cupp's methods for the reasons analogous to the ones indicated by Purdy, i.e. in order to prevent overheating of the sensitive biological sample, because the analysis is performed by using radiation in thermal range (mid-IR frequencies).

Since the measurement path is defined by penetration of the mid-IR incident radiation and therefore defined the output data, it would have been obvious for any person of ordinary skill in the art to optimize the penetration depth (measurement path) in order to obtain the most accurate results by comparing with the reference data.

14. **Claims 52-55** are rejected under 35 U.S.C. 103(a) as being unpatentable Lillenfeld-Toal as evidenced by Peralta in view of Cupp and Purdy, as applied to claims 28-51 and 56 above, and further in view of Rule et al. (US 2003/0040683 A1) (Rule).

Lillenfeld-Toal as evidenced by Peralta in view of Purdy and Cupp do not specifically disclose the second modulation technique, which comprises e.g. modulating of laser emitted signal with a specific frequency, such as in the range of 0.1 Hz-10 Hz, specifically 3 Hz.

Rule discloses "site selection for determining analyte concentration in living tissue" (Title) with the analyte being glucose and the analytical method - IR spectroscopy. In particular, Rule teaches: "[0152] The radiation emitted from the source 220 is in one embodiment modulated at a frequency between about one-half hertz and about one hundred hertz, in another embodiment between about 2.5 hertz and about 7.5 hertz, in still another embodiment at about 50 hertz, and in yet another embodiment at about 5 hertz. With a modulated radiation source, ambient light sources, such as a flickering fluorescent lamp, can be more easily identified and rejected when analyzing the radiation incident on the detector 250".

It would have been obvious for a person of ordinary skill in the art to further modify the method of Lillenfeld-Toal/Peralta-Cupp-Purdy by applying the second modulation technique,

such as the one disclosed by Rule, i.e. modulating radiation emitted by the IR source with the frequency within 0.1Hz-10 Hz range, because of the same reasons as indicated by Rule, e.g. in order to identify interfering radiation sources and correct for possible errors. It would have been obvious for a person of ordinary skill in the art to optimize the frequency of modulation within this range, and choose the frequency of 3 Hz for specific IR sources.

It would have been obvious for a person of ordinary skill in the art to substitute IR chopper, which blocks IR radiation, with the IR absorbing material, because it gives the same effect of preventing IR radiation from reaching the sample, and thus prevents overheating the sample.

15. **Claims 57-69** are rejected under 35 U.S.C. 103(a) as being unpatentable Lillenfeld-Toal as evidenced by Peralta in view of Cupp and Purdy and Sterling et al. (US 6,025,597, IDS) (Sterling).

Combined teaching of Lillenfeld-Toal as evidenced by Peralta in view of Cupp and Purdy can be read in paragraph 13 of the present Office action.

Lillenfeld-Toal/Peralta-Cupp-Purdy do not specifically disclose using spectral filtering for discrete detecting the signals at discrete wavelength bands of glucose.

Sterling discloses a wavelength selection system for selecting specific wavelengths of IR spectra, specifically discrete infrared bandpass filters (col. 10, lines 46), indicating the following:

> "The use of a specific set of bandpass filters restricts the instrument to analyzing only pre-selected wavelengths. The use of the FTIR allows the optical measurements of all wavelengths. When using an FTIR the final analysis wavelengths are selected in the signal processing computer. Therefore an instrument built with discrete filters is dedicated to measuring a predetermined compound, e.g. glucose, while an instrument built using an FTIR can be directed via software modifications to measure any of a number of compounds such as glucose, alcohol, etc." (col. 10, lines 57-67).

Thus, Sterling provides direct disclosure for both types of methods, i.e. the method of using FTIR instrument with post-detected processing the signals related to the analyte, e.g. glucose, or method of using spectral filters build-in into the IR spectrometer for the specific analyte, e.g. glucose, which makes the modification of Lillenfeld-Toal/Peralta-Cupp-Purdy' method in light of Sterling obvious for a person of ordinary skill in the art.

All filtration methods for the biological samples, specifically blood, recited in the dependent claims, are conventional for preparation of the sample for IR analysis, and therefore are obvious for a person of ordinary skill in the art.

Response to Arguments

16. Applicant's arguments filed 09/15/08 have been fully considered but they are not persuasive.

First, the examiner would like to notice that the Applicants did not respond to the objection to the previously amended claims as introducing new matter into the disclosure. The term "optical sensor" or "optical detector" have not been disclosed in the specification, and therefore comprise new matter for the instant application.

Regarding double-patenting rejection, it is not in examiner's authority to hold the rejection in abeyance until the allowable subject matter is indicated.

Objections to the claims are withdrawn.

Regarding rejection of claims 19-22 under 35 U.S.C. 112, first paragraph, the examiner failed to find the amendment to the claims indicted by the Applicants in their remarks, i.e. "measured using methods other than IR absorption". The rejection will be withdrawn as soon as the claims are amended in the way indicated in the remarks.

There are remaining issues regarding claims rejection under 35 U.S.C. 112, second paragraph, which were not addressed by the Applicants.

Regarding rejection of claims 1-5, 11 and 16-22 as being anticipatory by Lillenfeld-Toal as evidenced by Peralta, the examiner modified rejection of claims in view of the amendment, and therefore the Applicants' arguments regarding anticipatory rejections over the prior art are moot.

Regarding claim 23, the examiner is not quite sure, as to what is meant by the Applicants' arguments that the prior art does not teach optical detection of the transmitted electromagnetic radiation. It appears from all own Applicants claims that generating an electrical signal requires optical detection of the transmitted electromagnetic radiation, which is what the prior art teaches. The examiner respectfully requests the Applicants to clarify their opinion regarding lack of teaching of optical detection in the prior art. The same is true for claims 25 and 26.

The rejections of other pending claims are modified in view of the amendment, which renders most of the Applicants' arguments moot.

Nevertheless, the examiner would like to indicate several points, which may clarify discrepancies in the Applicants' and examiner's positions regarding the subject matter of the pending claims.

First, the Applicants appear to put a significant weight to the difference between FTIR technique and the technique which uses spectrally pre-filtered detection of glucose in complex biological samples, such as blood. However, spectrally pre-filtered detection of glucose at discrete wavelength ranges is known in the art, as demonstrated by Clarke's and Sterling's references. The examiner also would like to emphasize once more that the expression "the optical detector measures the intensity of radiation at less than 10 discrete wavelength bands", as recited e.g. in claim 28, is not a definite expression, as is clear from Sterling's disclosure, since such detection can be obtained by totally different methods, e.g. by obtaining FTIR spectra with the mathematical processing of raw data, or by using in-build spectral filters. Therefore, the statement, that the recitation of claim 28 is not related to FTIR spectrometry does not look convincing.

As to the Applicants' arguments regarding newly amended claims, the examiner obviously could not predict the Applicants' amendment and apply the prior art, on which newly amended claims would read.

As to the motivation for using Purdy's chopper in several references disclosing FTIR analysis, which leads to overheating the sample, the examiner is not quite clear, as to why the motivation to reduce overheating the sample by using the chopper is not a proper motivation, when this problem is well known in the art? If IR radiation can burn the animal, it obviously can overheat the biological sample, such as blood, and therefore should be avoided in any case. Furthermore, the motivation for combining references should not come from the Applicants' own disclosure. On the contrary, a different motivation for combining references confirms lack of hindsight for combing the references by the examiner.

If the Applicants find it helpful to discuss issues raised in the present Office action with the examiner, the examiner respectfully invites the Applicants for a telephone interview.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yelena G. Gakh/
Primary Examiner, Art Unit 1797

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